

## 8. How Supplied / Storage and Handling

The different strengths and physical description of the medicine are listed here with the required temperatures for proper storage to ensure the medicine's effectiveness until its expiration date.

## 9. Patient Counseling Information

Patients should read this section carefully. This section is intended to help inform healthcare professionals about the medicine they are prescribing for their patients. They should provide this important information to their patients at the time of prescribing. Additionally, pharmacists counsel the patient or caregiver if the medicine is dispensed for the first time or if the dosage has changed.

## What if I have questions?

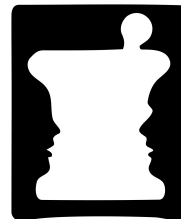
If you have questions, you should discuss them with your physician, pharmacist, or other healthcare provider at the time of service.

If you have additional questions, remember to **Ask Your Pharmacist!**

This information was based on material prepared by the U.S. Food and Drug Administration (FDA) and provided by:

California State Board of Pharmacy  
1625 N. Market Blvd., Suite N 219  
Sacramento, CA 95834-1924  
(916) 574-7900  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

Be Aware  
&  
Take Care



Talk to  
Your  
Pharmacist

# New Easier-to-Read Prescription Drug Information



Each year, approximately **2.2 million preventable adverse events** (illnesses and emergency hospital admissions) and more than **106,000 deaths** occur in U.S. hospitals\*, many as a result of confusing medical information. Consequently, the U.S. Food and Drug Administration (FDA) has directed drug manufacturers of new or recently approved prescription drugs to make the information provided with these drugs easier-to-read, less complicated and/or confusing, making it more useful to both physicians and patients.

\*Institute of Medicine, National Academy Press 2000

**While much of the material included with prescription drugs is directed toward health professionals, it also includes easy-to-read information that is very important to the patient or patient's caregiver.**

## What is Prescribing Information?

The prescribing information approved by the FDA contains information necessary for the safe and effective use of a prescription drug; it answers such questions as:

- **What diseases or conditions does the drug treat?**
- **What are the risks?**
- **What dose is needed?**
- **Which patients should not receive the drug?**
- **What other drugs should not be taken together with the drug?**
- **What side effects can occur?**
- **How should the drug be stored?**

## Some Highlights of the Prescribing Information

### 1. Drug Name/Form and Black Box Warning, if any

The first item of the prescribing information is the name of the medicine and its description (e.g., capsules, tablets, liquid), followed by a warning enclosed in a black line box **if** the medicine can cause life-threatening reactions or mental changes, such as thoughts of suicide.

**Black line boxed warnings are serious and should be read by both the prescriber and the patient or patient's caregiver.**

### 2. Indications and Usage

This section describes the symptoms or conditions that this prescription is intended to treat. It also lists and describes important limitations on the drug's use.

### 3. Dosage and Administration

The proper dosage amount for the condition to be treated is listed along with information about how to take the medicine. For example: *50 mg once daily with food*.

### 4. Contraindications

A contraindication is a condition or factor that increases the risk involved in using a particular drug. This section lists any conditions or disorders that should **not** be treated with this particular medicine.

### 5. Warnings and Precautions/ Adverse Reactions

This section lists any unwanted and/or dangerous results from the drug's use. It also recommends the monitoring of the patient's reaction to the drug for any symptoms of such results.

Potential adverse reactions (illnesses, conditions or mental changes caused by the drug) are listed in this section, followed by directions for reporting an adverse reaction to the drug's manufacturer or to the FDA.

### 6. Drug Interactions

Listed here are any prescription or over-the-counter medicines or food supplements that should not be taken with this drug.

### 7. Overdosage

Information in this section relates to cases and outcomes of overdoses of this drug. A poison control number is also provided.